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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/054,300

01/22/2002

Takeshi Imanishi

01834CIP/HG

5360

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7590

06/27/2006

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,300

Applicant(s)

IMANISHI ET AL.

Examiner

Traviss C. McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/19/02, 3/9/04, & 4/1/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

At the onset the examiner would like to note that applicant cannot rely upon the foreign priority papers to overcome any rejections based upon publications filed before the instant filing date (1/22/2002) as a translation of said priority papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. As such, the filing date of the instant application for the purposes of art rejections is considered to be January 22, 2002 until applicants have met the requirements as set forth in 37 CFR 1.55.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on April 26, 2006 is acknowledged. The traversal is on the ground(s) that another application in the art unit examined pyrimidine and purine bases together and that nucleosides were examined together with oligonucleotides. This is not found persuasive because all applications are known to be treated on their own merits. Applicants also argue that groups I and III are classified in the same class, and groups IV and V in the same class and subclass. It is noted that the examination and search of the claims in a patent application require more than just a search of a class, or a subclass. As such, because 2 groups are classified in the same class, does not mean they are not patentably distinct. For example, class 514 subclass 44 has 2,665 patents issued therein, and these are clearly not all of the same scope or obvious variants of each other.

Applicants then traverse the species requirement because "it is not a species requirement of the type set forth in the 3rd paragraph of MPEP 803.02". Applicants then state that "to the

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extent that the restriction requirement is not consistent therewith (to MPEP 803.02), it is respectfully traversed". This is not seen to be persuasive as applicants have not pointed out that which they actually believe the examiner did wrong. Stating that the restriction is improper for reasons which were not followed in the MPEP is not seen to be a persuasive argument.

Moreover, MPEP 803.02 states:

As an example, in the case of an application with a Markush-type claim drawn to the compound $* > X - R <$, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, $** > XA, XB, XC, XD, \text{ or } XE <$. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration.

This is the exact situation as in the instant application. Applicants have a compound with various R groups, and the examiner required applicants to pick a single species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

It is noted that after searching the elected group and reviewing the art, the examiner has withdrawn the restriction requirement between Groups I and II, as such, both purine and pyrimidine bases will be examined. Moreover, it is noted that applicants elected Group I, but a species from Group II. In the future applicants should elect a species from the elected group to avoid any possible amendments which would be considered non-responsive.

Additionally, it is noted that due to the 102(b) rejection set forth below, which anticipates the elected species, claims 24-28 are withdrawn pursuant to MPEP section above ("If on

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examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration”).

An action on the merits of claims 1-10 and 23 is contained herein below.

Claim Objections

Claim 1 is objected to because of the following informalities: the phrase “R^{4a} and R^{4b} is the same...” would be more properly read as R^{4a} and R^{4b} are the same...”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states that “R¹ is the same or different, and each represents...”. This phrase is confusing as there is only 1 R¹, so how could the sole R¹ group be different? Changing the phrase to read “wherein R¹ is selected from the group consisting of...” would be seen to obviate the instant rejection. It is noted that applicants also state that “wherein R³ is the same or different”, and changing this as above would obviate the rejection for this phrase. All claims which read in this manner are indefinite.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Obika et al. (“Synthesis of a conformationally locked AZT analogue, 3'-azido-3'-deoxy-2'-O,4'-C-methylene-5-methyluridine”, Tetrahedron Letters, 40, 6465-6468, 1999).

The claims above are drawn to the elected species, as set forth supra, being 3'-amino-3'-deoxy-2'-O,4'-C-methylene-5-methyluridine.

Obika et al. disclose the elected species, see page 6466 compound 1b in figure 2.

As set forth supra, applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III
June 22, 2006
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A handwritten signature in black ink, appearing to be 'Traviss C. McIntosh III', written in a cursive style with a long horizontal stroke extending to the right.